

The Kerry logo is located in the top right corner of the page. It consists of the word "KERRY" in a bold, white, sans-serif font, set against a dark blue rectangular background with a thin white border. The background of the entire page is a collage of various colored and shaped pills and capsules, including red, blue, yellow, pink, and white, with some having distinct markings like a cross or a score line. The left side of the page features a light yellow background with wavy, horizontal bands of varying shades of yellow and orange.

KERRY

The SheffCoat logo is positioned in the lower-left quadrant of the page. It features the text "SheffCoat" in a white, sans-serif font, with a trademark symbol (TM) to the right. The text is centered within a dark red, hexagonal shape with a white border.

SheffCoat™

Aqueous Based Coating Systems

Customized Immediate Release and
Enteric Film Coating Systems

www.SheffieldBioScience.com

A Name You Know Can Trust

For more than 75 years, we have earned our reputation for reliability and excellence in serving the biotech, pharmaceutical and nutrition markets by delivering unsurpassed product value, enhanced opportunities for supply chain consolidation, and new technology innovation. We bring together our superior products with new innovative solutions and market-driving alternatives to help our customer succeed in today's challenging global marketplace.

As part of the Kerry Group, a \$6 Billion leader, we can provide you the global technical service, regulatory and application support whether this is in the development process, or trouble-shooting commercial production challenges.

We make it our business to exceed our customers' expectations every day. We collaborate directly with formulators in the development of new drugs and delivery systems. We understand the requirements and regulations needed to succeed.

SheffCoat™ Benefits

- Pre-blended, ready-to-use dry clear or colored coatings that optimize performance and efficiency
- Complete line of cost effective aqueous coating systems
- Based on industry standard polymers, pigments, and plasticizers that meet all regulatory requirements
- Applied with standard film coating processes and equipment
- R&D application labs for custom & collaborative formulation development
- Match or exceed performance of current coating system
- Precise color matching of existing coating system and assurance of batch to batch color consistency



SheffCoat™ : The Standard of Comparison

Building on 75 years of innovation, commitment and reliability as a world class excipient supplier, Kerry has created a one step, ready-to-use system to match your existing coating and color, while offering a full spectrum of best-in-class, cost effective solutions.

SheffCoat™ film coating systems are based on industry standard, regulatory accepted polymers, pigments and plasticizers that are applied with standard film coating processes and equipment. With our extensive knowledge and experience we can match or exceed the functionality of any competitive coating system as well as custom match or create any desired color. We provide formulation, technical, regulatory and quality support through every step of your development, scale-up and production process.

Manufacturing Expertise

SheffCoat™ coating systems are manufactured in Norwich, NY which is a CFR 210-11 Registered Drug Establishment, and Vadodara, India. We are committed to exceeding the cGMP expectations of our pharmaceutical customer base with our extensive quality assurance programs. Each batch is produced in accordance within approved specifications and are GMP/GLP compliant with IPEC guidelines as well as regional requirements globally.

Our individual and isolated manufacturing suites have separate air handling systems. We have various blenders allowing for accurate scale-up and enabling batch sizes up to 1,000 kg.

Global Technical Support

Our core technical expertise and extensive knowledge in industrial pharmaceutical tablet coating enables us to support our customers in optimizing SheffCoat™ performance and efficiency. We are available to assist customers with on-site coating trials and problem solve with production issues.

Regulatory and Quality Assurance

Kerry has a dedicated regulatory group to ensure product compliance to global regulatory requirements. Our regulatory team provides full customer support to customers in every step of the process including regional regulatory agency compliance, vendor forms, and audits to complete formulation changes.

Changing to SheffCoat™ assures seamless changes from your current formulations' quality and performance while improving your cost competitiveness, and flexibility.

*Drug Master Files are available.



Individual and Isolated suites have separate air handling systems.



Various blenders with liquid addition and high sheer mixing.



Accurate scale-up and multiple batch sizes.

New Product Formulation

When you need something unique, Kerry has the technical and applications expertise and is ready to work with your R&D team to create a unique solution.

Our state of the art pilot plants and application labs in the US, Brazil, Turkey, and India are fully equipped to perform tablet functionality testing to ensure our products conform to the highest standards. Our application experts will collaborate with you to develop a customized formulation that will optimize performance and efficiency while using ingredients that meet all regulatory and consumer requirements.

Kerry's application technicians can provide solutions to solve coating issues such as:

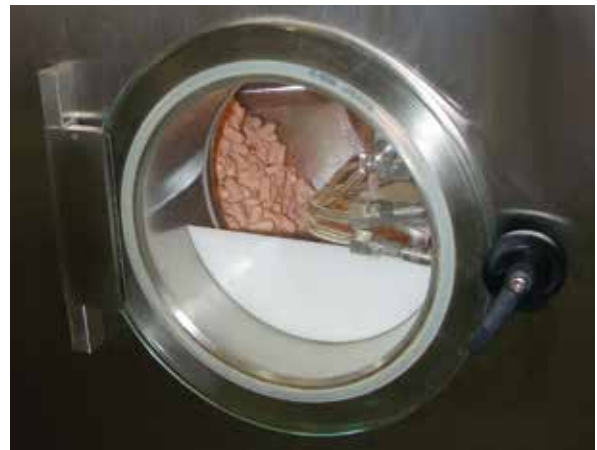
- Soft or friable cores
- Uneven or inconsistent cores
- Heat sensitive APIs
- Moisture sensitive APIs
- Process efficiency requirements

Color match sources can include, but are not limited to:

- Existing Formulations
- Previously Coated Tablets
- Pantone Number
- PDR or On-Line References

R&D/Application Support

- Custom collaborative coating development capabilities
- Color matching of existing coating system
- Pilot scale coating trials
- Extensive knowledge in scale-up into manufacturing
- Complete tablet functionality testing capabilities
- Capabilities to match or exceed performance of current coating system



SheffCoat™ Standard Color Collection

Colored tablet coatings provide brand recognition and dose discrimination functions, as well as mask the tablet core. Kerry has coatings to meet label requirements, regulatory requirements and stability needs for all regions. We offer a portfolio of off-the-shelf colors that can also be customized to create a distinctive color.

Need to precisely match an existing color? We understand the importance and we get it right. Visual and spectrophotometric color match specifications are part of every product.

The below are standard collection colors. Contact us for customized colors per your requirements.



*contains Iron Oxide

Packaging and Samples

All of our samples are shipped with coated placebos and a sufficient quantity of coating powder formulations so you can evaluate the color prior to performing any coating trials.

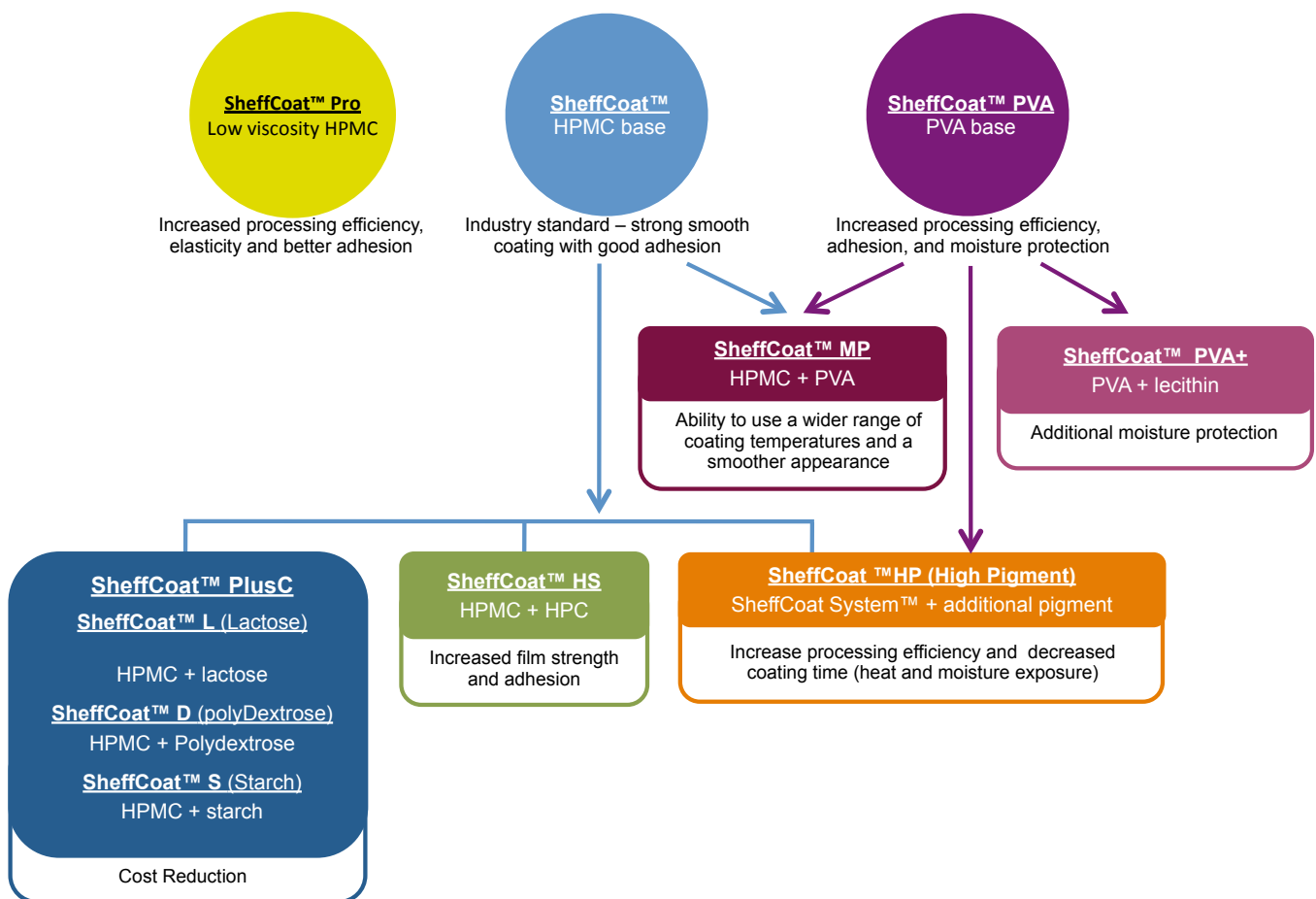
SheffCoat™ is packaged in a 25kg poly lined, tamper evident boxes. Customized packaging and batch sizes available upon request.

Standard sample is 0.5 kg, but larger samples are available upon request.



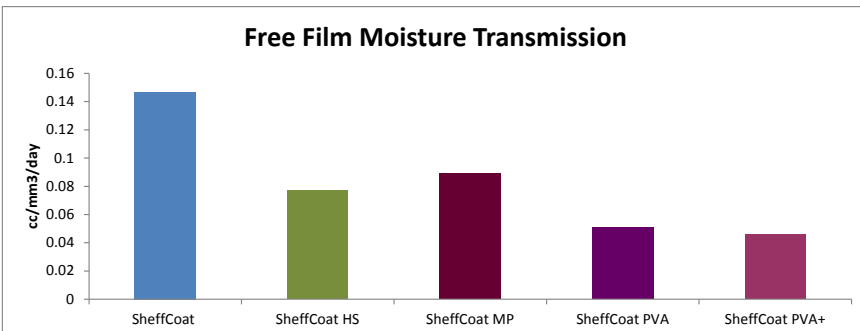
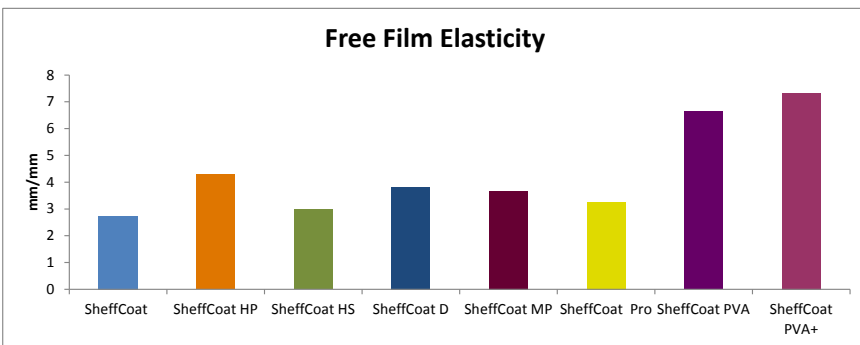
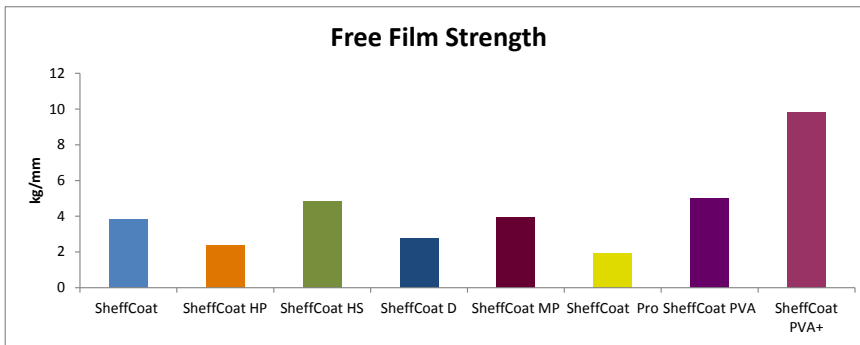
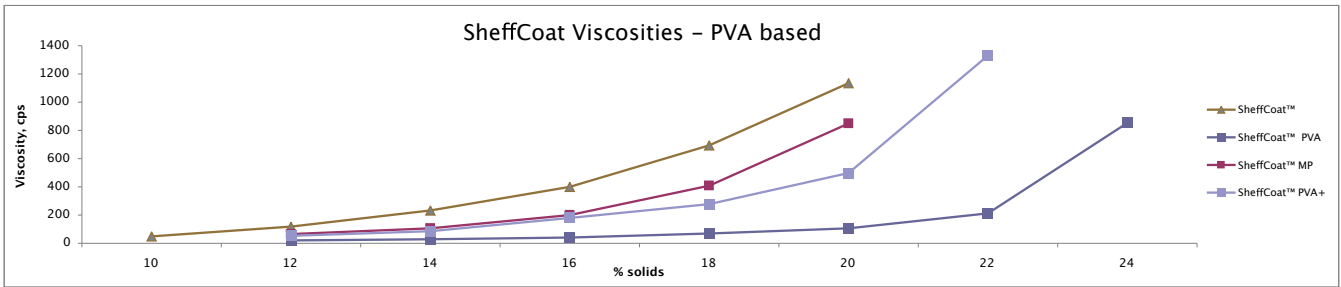
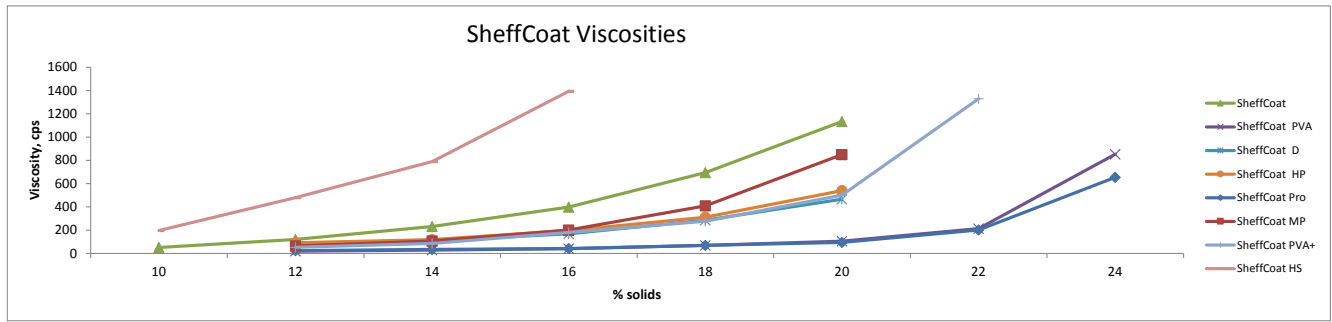
SheffCoat™ Immediate Release Offerings: Coatings Overview

SheffCoat™ Immediate Release film coatings allows the customer to select from numerous plasticizers and a wide range of colorants to customize a film coating that is compatible with your API and regional regulatory requirements. We offer a variety of different viscosities and film strengths to exactly match your existing film coating or customize a film coating that will provide superior film performance and adhesion while providing excellent logo definition without compromising disintegration time or other important tablet properties.



SheffCoat™ Optimization Matrix

	Polymer	Moisture Sensitive API - aqueous coating	Moisture Sensitive API - alcohol or solvent coating	Temperature Sensitive API	API sensitive to plasticizer interaction	Waxy or poor adhesion cores	Soft tablets (herbal formulations)	Low Viscosity/ high solids solution	Improved Logo Definition	Cleaner label	Prop 65 Restrictions	Titanium dioxide free	Natural Pigments	Taste or Odor Masking	Glossy Finish	Gloss topcoat	Precoat for friable cores	Precoat for enteric coating	Aqueous Enteric Coating	Alcohol or Solvent Based Coating
SheffCoat™	HPMC							X	X	X	X	X		X	X		X			
SheffCoat™ Pro	HPMC			X				X	X	X								X		
SheffCoat™ PVA	PVA	X					X	X	X			X	X	X		X				
SheffCoat™ PVA+	PVA	X																		
SheffCoat™ HS	HPMC+ HPC	X			X	X	X				X						X			
SheffCoat™ L	HPMC+ Lactose					X			X											
SheffCoat™ D	HPMC+ Polydextrose							X							X					
SheffCoat™ S	HPMC+Starch																			
SheffCoat™ MP	HPMC+PVA					X			X		X		X							
Sheff HP™ (High Pigment)	HPMC and/or PVA			X																
SheffCoat™ ENT	Methacrylate copolymer																		X	
SheffCoat™ EC	HPMC+ Ethylcellulose		X											X						X



Placebo's were coated to 3% weight gain.
PEG was used as the plasticizer.

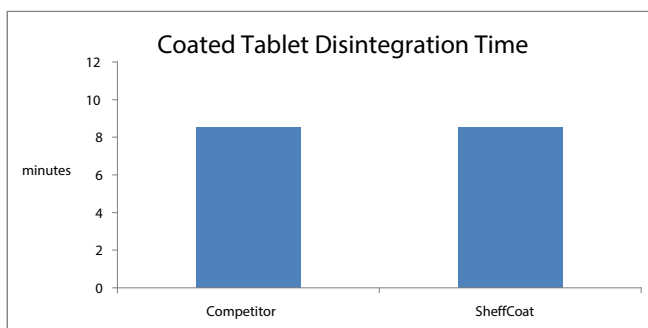
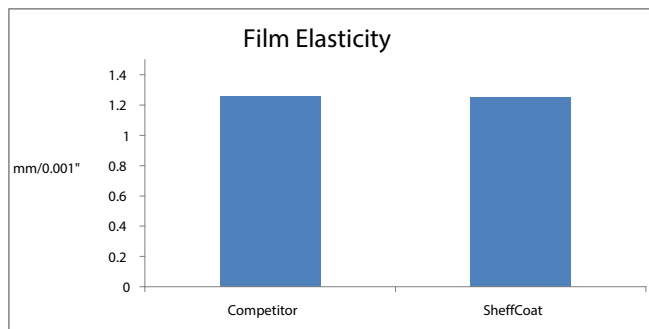
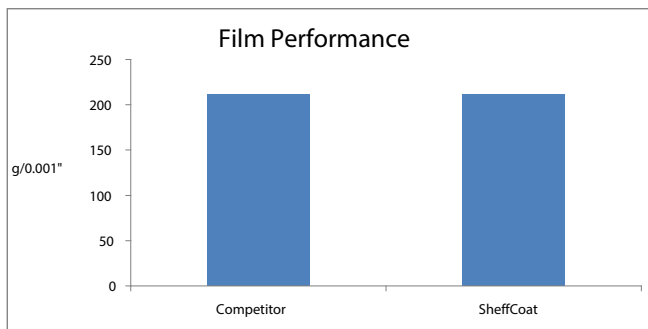
The Original SheffCoat™



- The most basic film coating; widely used across the pharmaceutical industry for decades
- Numerous plasticizers available; plasticizers chosen to be compatible with API and regional regulatory requirements, or label requirements
- Wide range of colors available; chosen to be compatible with API and regional regulatory requirements, or customers preferences
- Different viscosities and molecular weights available
- SheffCoat™ is equivalent in performance and appearance to other HPMC coatings on the market

Film Performance

SheffCoat™ film coating system provide exact matches to competitive products with comparable formula and functionality without compromising important film attributes.



SheffCoat™ PVA

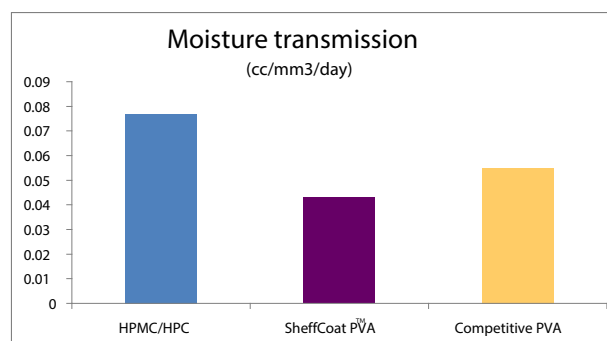
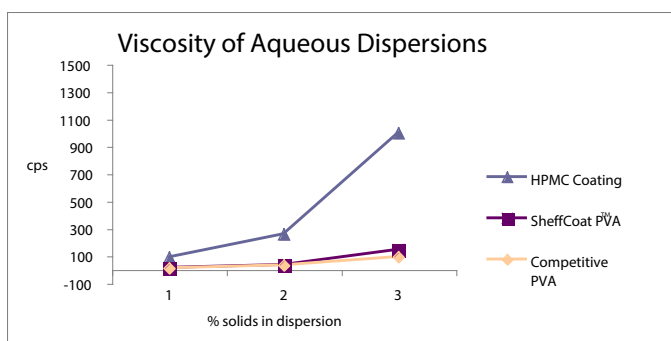


- Applied with 20% solids spray suspensions for improved efficiency over HPMC
- Superior film coating to HPMC
- Ideal “slip” for bottle packaging equipment and blister pack machines
- No change in tablet dissolution and compared to HPMC
- Excellent adhesion properties



- SheffCoat™ PVA+ provides the same benefits of a traditional PVA coating but contains lecithin for additional moisture protection.

Film Performance



SheffCoat™ Pro

HPMC Based Coating Platform

SheffCoat™ Pro is a low viscosity HPMC film coating that provides increased processing efficiency, elasticity and adhesion over traditional HPMC systems. It can be sprayed at a significantly lower temperature than PVA and HPMC allowing for increased energy savings and making it ideal for heat sensitive APIs. SheffCoat™ Pro is an ideal high efficiency coating when PVA based coatings cannot be used due to regulatory requirements, process temperature, or plasticizer considerations.

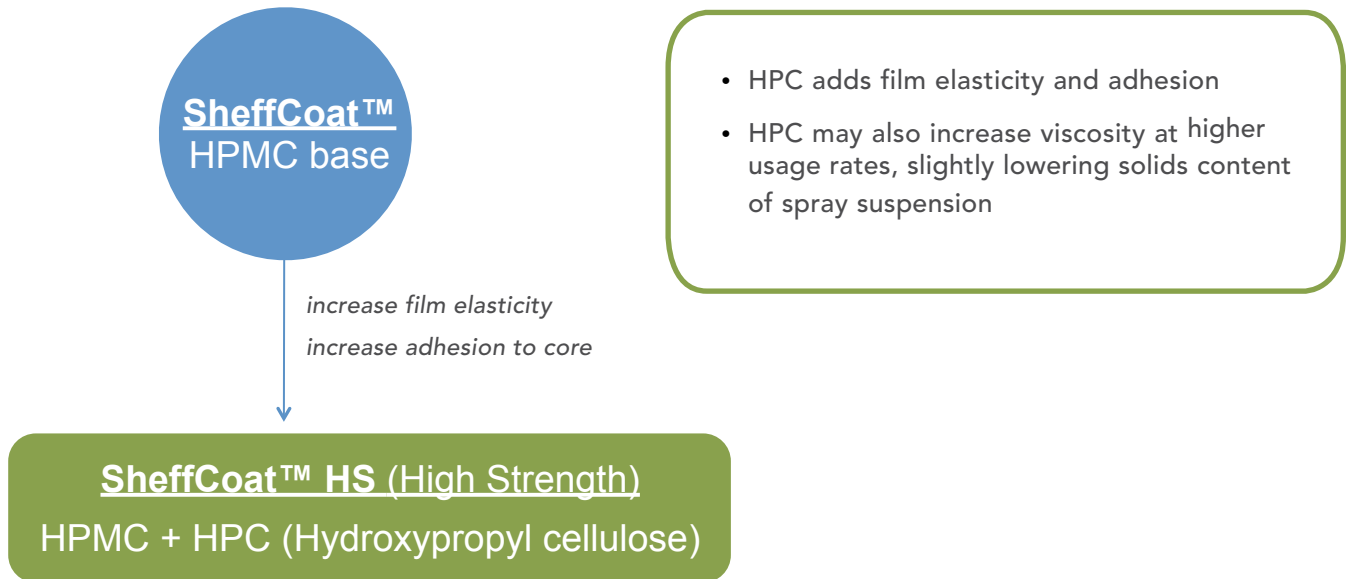


- Applied at 25% solids (up to twice as fast as traditional HPMC systems)
- Utilizes VLV – a low viscosity HPMC without the brittle characteristics of E3.
- Adhesive and elastic coating with good appearance and excellent logo definition
- Considered a trouble shooting coating
- Sprayable at lower temperatures allowing for increased energy savings and ideal for heat sensitive APIs

SheffCoat™ HS

HPMC Based Coating Platform with Increased Film Elasticity and Adhesion

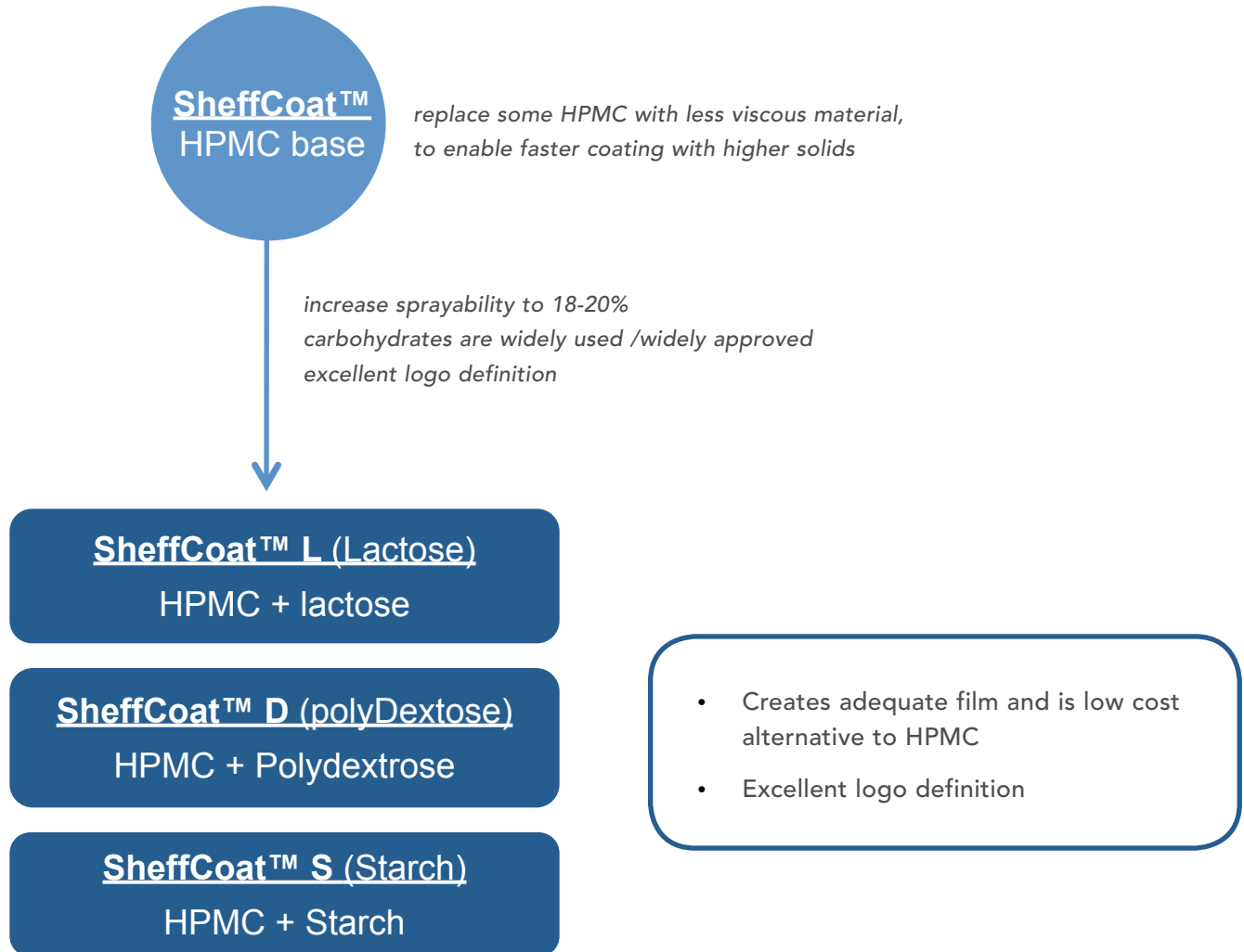
Some tablets have softer cores and may need a very durable coating with increased adhesion in order to ensure the tablet core does not erode during the coating process. There are also certain APIs that are extremely sensitive to moisture. The addition of HPC provides improved film characteristics to overcome these issues.



SheffCoat™ PlusC Systems

HPMC Based Coating Platform with Improved Processing Efficiency and Less Cost

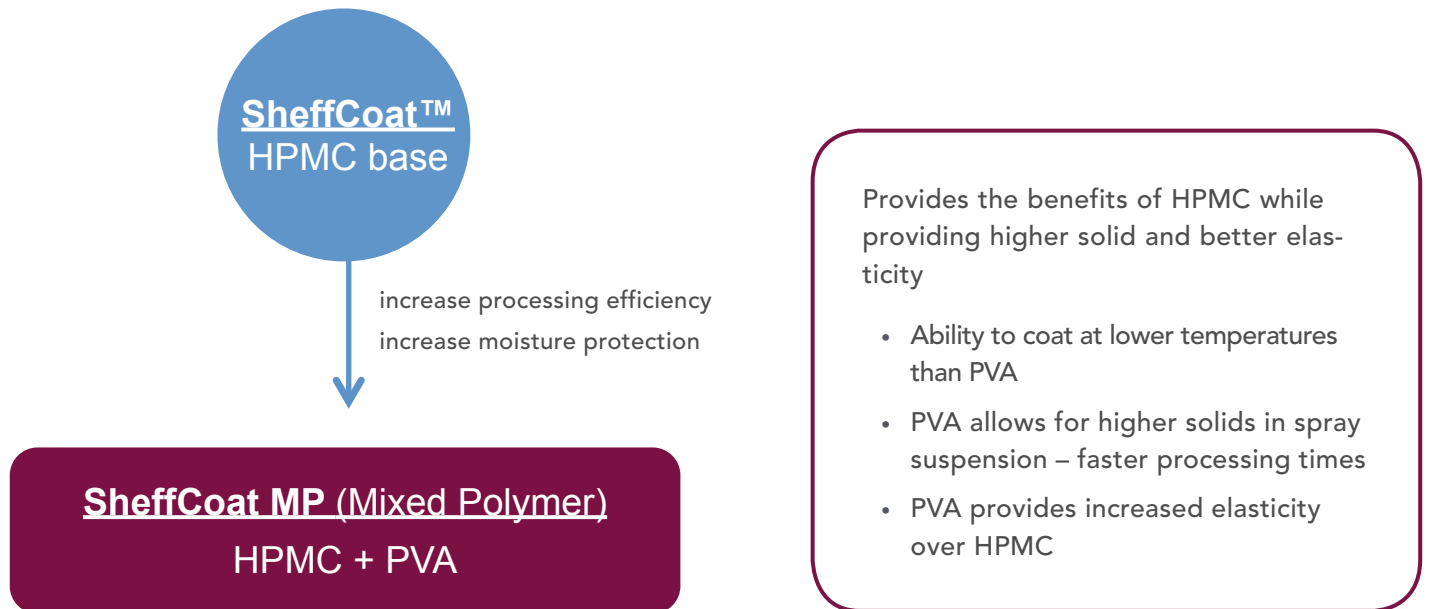
The need for higher than 15% solids spray suspension is desired when faster processing times are needed because the tablets cannot have prolonged exposure to heat and moisture. The addition of a carbohydrate provides the increased processing efficiency without using PVA.



SheffCoat™ MP

HPMC Based Coating Platform with Improved Processing Efficiency and Film

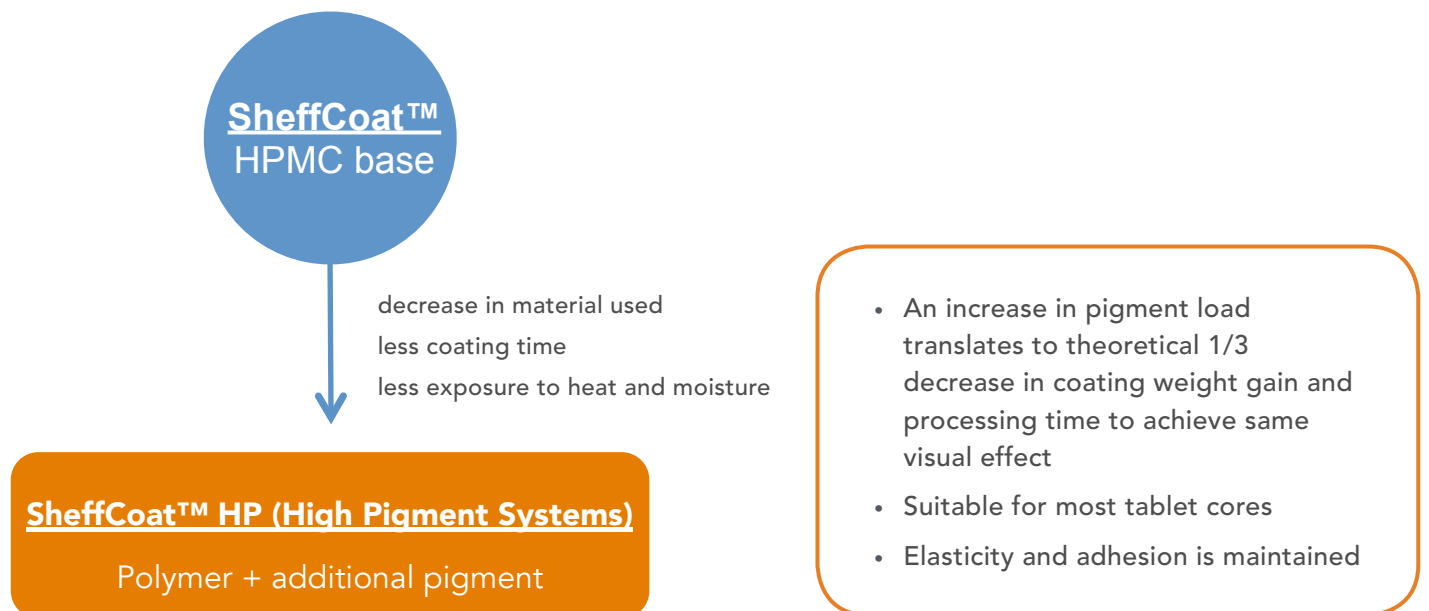
It is possible to increase processing efficiency of a basic HPMC formulation while maintaining film strength and adhesion. Instead of replacing HPMC with a carbohydrate, a high performing film forming polymer such as PVA is used in combination.



SheffCoat™ High Pigment Systems

HPMC Based Coating Platform with Increase Pigment Loading

Increasing the levels of pigment in the formulation provides greater efficiency while maintaining the the film performance.



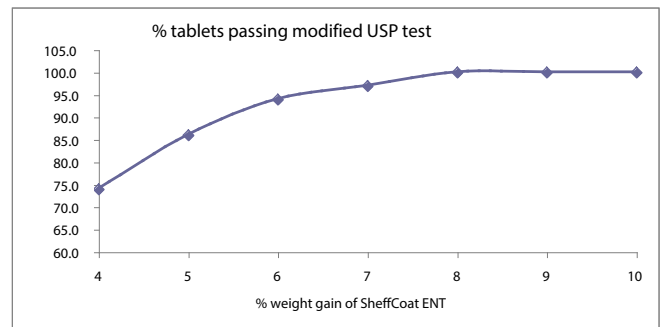
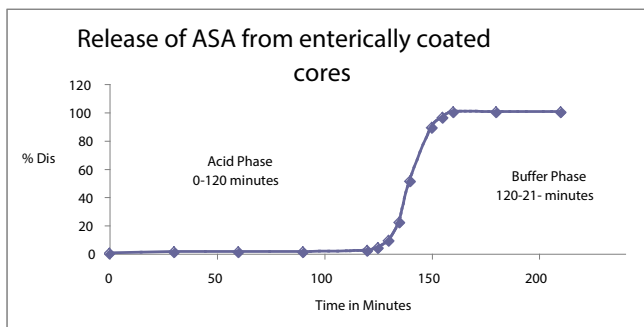
SheffCoat™ Enteric Film Coatings

SheffCoat™ ENT is a functional delayed release or enteric film coating that releases the API at a specific pH and/or area of the digestive tract.

SheffCoat™ ENT
Methylmethacrylate Copolymers

- Complete ready-to-spray powder formulations
- Consistent and reproducible delayed release performance
- Targeted drug delivery for applications including tablets, granules, and beads
- pH Dependent Release
- Solubilizes at pH 5.5
- Variety of plasticizers available

Film Performance



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MC/Coating/082015

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